

REMARKS

Claims 1-7, 14-21, 29-45, 54-59 are pending for examination with claims 1, 29, 37 and 54 being independent claims. No new matter has been added.

Applicants acknowledge the courtesies extended to Mr. James M. Hanifin, Jr. and Ms. Amy F. Mendel during the telephone interview with the Examiner on January 28, 2004. The substance of the discussion during the interview is incorporated into the following remarks.

Applicants respectfully traverse each of the rejections presented in the Final Office Action of October 31, 2003 for the reasons set forth in their prior response of August 6, 2003, which is incorporated herein by reference, and for the reasons discussed below. Applicants also submit herewith the declaration of Stephan N. Eldridge (hereafter the "Eldridge Declaration") to provide factual support for their positions. Mr. Eldridge has extensive experience in the soft tissue repair prosthetics industry. (See Eldridge Declaration, paragraph 2). He is familiar with the level of knowledge possessed by those of ordinary skill in the art of soft tissue repair prosthetics as of the filing date of the present application. (See Eldridge Declaration, paragraph 5). As set forth in his declaration, Mr. Eldridge disagrees with the Examiner's positions regarding the teachings of Mulhauser (U.S. Patent No. 5,766,246).

Rejections Under 35 U.S.C. §103

*Claims 1-7, 14-17, 20, 29-35, 37-44, 54 and 58*

Claims 1-7, 14-17, 20, 29-35, 37-44, 54 and 58 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Mulhauser (U.S. Patent No. 5,766,246). Applicants respectfully traverse this rejection.

Independent claims 1, 29, 37 and 54 are each directed to an implantable prosthesis including, *inter alia*, a layer of repair fabric and a barrier layer configured to inhibit the formation of adhesions between at least a portion of a surface of the repair fabric and adjacent tissue and organs. The layer of repair fabric has an outer peripheral edge or an outer margin with an outer peripheral edge.

Claim 1 recites that the prosthesis also includes a peripheral barrier that inhibits the formation of adhesions with adjacent tissue and organs.

Claims 29 and 54 recite that the entire thickness of the outer peripheral edge is adapted to inhibit the formation of adhesions thereto.

Claim 37 recites that the outer margin has been melted and resolidified to render the entire thickness of the outer peripheral edge resistant to the formation of adhesions with tissue and organs.

Mulhauser discloses an implantable prosthesis including a layer of repair fabric (12) and a semi-rigid frame or ring (14) for maintaining the prosthesis in a predetermined shape. In one embodiment shown in Figs. 2a-2b, the ring (14) extends about the periphery of the repair fabric. In another embodiment shown in Figs. 4a-4b, the prosthesis includes a barrier layer (36) to isolate the fabric (34) from sensitive tissues and organs. (Col. 5, Lines 24-25). As illustrated, the barrier layer extends beyond the ring to cover portions of the fabric also extending beyond the ring.

The Examiner contends that the ring (14) forms a peripheral barrier having an outer margin that has been melted and resolidified. The Examiner also contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Figs. 2a-2b prosthesis by adding the barrier layer (36) of the Figs. 4a-4b prosthesis to prevent undesirable adhesions with nearby organs, thereby rendering the claims obvious. Applicants respectfully disagree.

Without acceding to the propriety of the modification suggested by the Examiner, the resulting prosthesis does not include either a peripheral barrier that inhibits the formation of adhesions, as recited in claim 1, or an outer peripheral edge adapted to inhibit the formation of adhesions thereto, as recited in claims 29, 37 and 54.

In the Office Action and during the telephone interview, the Examiner presented several reasons to support his position that the ring (14) of Mulhauser inhibits adhesions thereto. More particularly, the Examiner asserted that [1] the ring may be formed from silicone and silicone does not promote tissue ingrowth; [2] the ring may be formed by melting and resolidifying the mesh; [3] Mulhauser only specifies that tissue ingrowth occurs through the mesh; and [4] the figures show a solid ring lacking interstices. Applicants respectfully disagree with each of these reasons and will address each one more fully below.

[1] Silicone Ring

As discussed during the interview and in the Office Action, the Examiner asserts that the ring (14) does not promote tissue ingrowth on the basis that it may be made of a silicone material. Applicants respectfully disagree.

As discussed during the interview, Mulhauser does not teach or suggest that the ring (14) has any type of adhesion inhibiting properties. (See Eldridge Declaration, paragraph 8). Mulhauser only indicates that the ring (14) may be formed from a polypropylene or silicone material. (See Mulhauser, Col. 4, Lines 60-61). Although a silicone material may be formed into a structure which inhibits adhesions with tissue and muscles, silicone material does not inherently or necessarily inhibit adhesions. Further, Mulhauser's teaching of an adhesion barrier (36) that may be formed of a silicone material does not lead to the conclusion that the silicone is adhesion resistant.

As explained during the interview, the adhesion resistant properties of a soft tissue repair prosthesis are affected by various factors including the surface texture and pore size of the material that forms the prosthesis or portions of the prosthesis. (See Eldridge Declaration, paragraph 9). Thus, a prosthesis may be either resistant to the formation of adhesions or promote tissue ingrowth and adhesions depending upon the particular structural characteristics of its material. (See Eldridge Declaration, paragraph 9). For example, a prosthetic material, including silicone, having a surface texture or porosity of approximately 10 $\mu$ m or more is not adhesion resistant, but rather is susceptible to adhesions with tissue or muscle. (See Eldridge Declaration, paragraph 9).

Mulhauser provides no teaching or suggestion as to any structural characteristics of a silicone ring that would determine its adhesion resistant properties. As indicated above, Mulhauser discloses only that the ring may be formed from a silicone material. However, the surface texture and porosity of a silicone ring (as well as a molded polypropylene ring) can vary depending on the specific design parameters of the mold used to form the ring. (See Eldridge Declaration, paragraph 10). Therefore, a molded silicone ring can promote tissue ingrowth and adhesions with tissue and muscle. (See Eldridge Declaration, paragraph 10). Thus, the fact that the Mulhauser ring may be made from a silicone material does not necessarily provide a ring that inhibits adhesions to tissue and muscle, such that one of ordinary skill in the art would not consider the Mulhauser ring, even if formed of silicone material, as necessarily being resistant to tissue ingrowth and adhesions to tissue and muscle. (See Eldridge Declaration, paragraph 10).

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Although Mulhauser teaches an adhesion resistant barrier layer (36) that may be formed of a silicone material, it does not necessarily follow that a ring formed of a silicone material is adhesion resistant. An adhesion resistant barrier layer, such as may be employed on the Mulhauser prosthesis, requires a microporous structure having a surface texture or porosity that is less than 10 $\mu$ m. (See Eldridge Declaration, paragraph 11). This is not an inherent property of the material itself, but varies depending upon the structure formed with the material, whether it is silicone or other material. (See Eldridge Declaration, paragraph 11). Concerning the barrier 36, Mulhauser discloses using Silastic® Rx Medical Grade Sheeting (Platinum Cured), which is a particular silicone sheet product fabricated to provide adhesion resistant properties. (See Eldridge Declaration, paragraph 11). Thus, the fact that a silicone elastomer may be employed as a barrier material does not support a conclusion that any structure formed from a silicone elastomer, such as the Mulhauser ring, is necessarily adhesion resistant. (See Eldridge Declaration, paragraph 11). One of ordinary skill in the art would recognize that an adhesion resistant barrier layer requires a microporous structure and that structures formed from a silicone elastomer are not necessarily microporous and adhesion resistant. (See Eldridge Declaration, paragraph 11).

## [2] Hot Forming the Ring

As discussed during the interview and in the Office Action, the Examiner asserts Mulhauser teaches a prosthesis with a peripheral barrier 14 having an outer margin that has been melted and resolidified. (See Mulhauser, Col. 4, Lines 64-65). Applicants respectfully disagree.

“Hot or cold forming” does not necessarily result in a structure that inhibits or is resistant to the formation of adhesions. Although Mulhauser indicates that the ring may be formed by hot forming a ring-shaped depression in the mesh sheet, this does not necessarily involve any melting and resolidifying of the mesh material. (See Eldridge Declaration, paragraph 12). Nevertheless, even when assuming, for the sake of argument only, that hot forming does involve some degree of melting and resolidifying of the outer margin, it does not necessarily follow that the entire thickness of the outer peripheral edge would be adapted to inhibit the formation of adhesions thereto. (See Eldridge Declaration, paragraph 12). Rather, the degree of melt would vary depending on a number of factors including die design, applied pressure, dwell time, temperature (heated die process) and frequency (sonic weld process). (See Eldridge Declaration, paragraph 12). Additionally, it is unclear as to where the ring-shaped depression would even be

formed (i.e., at the outer peripheral edge or spaced inward from the peripheral edge) on the fabric layer. (See Eldridge Declaration, paragraph 12). Thus, one of ordinary skill in the art would recognize that hot or cold forming a ring-shaped depression does not necessarily result in the entire thickness of the outer peripheral edge being adapted to inhibit to adhesion formation. (See Eldridge Declaration, paragraph 12).

### [3] Tissue Ingrowth Through Mesh

As discussed during the interview and in the Office Action, the Examiner asserts that Mulhauser teaches tissue ingrowth only through the mesh fabric. The Examiner, therefore, concludes that the ring is adhesion resistant. Applicants respectfully disagree.

Although the only discussion in Mulhauser concerning tissue ingrowth is in conjunction with the mesh fabric, Mulhauser does not teach that tissue ingrowth will occur only through the mesh fabric to the exclusion of all other components of the prosthesis, including the ring. The fact that Mulhauser is silent as to the adhesion resistant characteristics of the ring requires the Examiner to establish that adhesion resistance is an inherent property of the ring. In this regard, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily follows from the teachings from the applied prior art. (See MPEP § 2112). As discussed above and set forth in the Eldridge declaration, adhesion resistance is not an inherent property of the Mulhauser ring. The mere fact that Mulhauser discusses tissue ingrowth in conjunction with the mesh fabric, but not the ring, does not provide any basis to support a position that the Mulhauser ring is adhesion resistant. Applicants respectfully submit that this is nothing more than a circular argument.

Notwithstanding the foregoing, as discussed during the interview, Mulhauser also discloses an adhesion resistant barrier layer 36 which isolates the mesh fabric 34 from sensitive tissue and organs. (See Mulhauser, Col. 5, Lines 20-37). Therefore, if one were to follow the Examiner's rationale, then the ring is susceptible to adhesions because the only disclosure of an adhesion resistant barrier is in conjunction with the barrier layer 36. Furthermore, as illustrated in Fig. 4(b), the adhesion resistant barrier layer 36 covers not only the tissue infiltratable mesh fabric 34, but also the ring 32. This arrangement suggests that the ring may also promote adhesion formation because the ring, like the tissue infiltratable mesh, is covered by the adhesion

resistant barrier when it is desirable to prevent adhesions between the prosthesis and sensitive tissue and organs.

In view of the foregoing, the fact that the only discussion of tissue growth in Mulhauser is in conjunction with the mesh fabric does not support the Examiner's position that the ring is adhesion resistant.

#### [4] Figures without Interstices

As discussed during the interview and in the Office Action, the Examiner also contends that the figures of Mulhauser support his position that the ring inhibits tissue ingrowth on the basis that the figures show a solid ring lacking interstices. Applicants respectfully disagree.

As discussed during the interview, nothing in the figures provide any indication that the ring is adhesion resistant. (See Eldridge Declaration, paragraph 13). As indicated above, the adhesion resistance of a material implanted in a body depends on the surface texture and porosity of the material and that tissue ingrowth can occur when the surface texture or porosity is approximately 10µm or more. (See Eldridge Declaration, paragraph 13). This amount of surface texture and porosity is microscopic and undetectable with the naked eye. (See Eldridge Declaration, paragraph 13). Thus, simply because the drawing in Mulhauser does not illustrate interstices does not indicate that the ring is resistant to tissue ingrowth or adhesions. (See Eldridge Declaration, paragraph 13).

Applicants also note that the figures of Mulhauser illustrate the ring 14 of Mulhauser using a surface symbol associated with materials having varying degrees of porosity which can be readily observed with the naked eye. For example, the Mulhauser ring is illustrated using the same surface symbol employed for various porous and relatively textured materials including, but not limited to, wood, insulation, synthetic sponge, cork, cheese and foam. (See MPEP §608.02). In this regard, materials that are porous and have surface texture even to the naked eye would be illustrated without pores and surface texture following Patent Office guidelines for drawing preparation. Thus, the fact that the Mulhauser figures do not illustrate the ring as being rough or porous does not lead to the conclusion that it is resistant to the formation of adhesions. Additionally, as indicated above, the degree of surface texture or porosity of a material that would allow tissue ingrowth and adhesions is microscopic and not even visible to the naked eye.

(See Eldridge Declaration, paragraph 13). Accordingly, the Mulhauser figures do not disclose an edge barrier which inhibits the formation of adhesions with sensitive tissue and organs.

In view of the forgoing, the rejection of claims 1, 29, 37 and 54 as being unpatentable over Mulhauser under §103 is improper and should be withdrawn. Claims 2-7, 14-17 and 20, claims 30-35, claims 38-44 and claim 58 respectively depend from claims 1, 29, 37 and 54 and are patentable for at least the same reasons.

*Claims 18, 19 and 45*

Dependent claims 18, 19 and 45 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mulhauser as applied to claims 1, 16, 37 and 44 above, and in further view of Sharber et al. (U.S. Patent No. 6,075,180). Applicants respectfully traverse these rejections.

Without acceding to the propriety of these rejections advanced by the Examiner, claims 18 and 19 and claim 45 respectively depend from independent claims 1 and 37 and are patentable for at least the same reasons set forth above.

*Claims 21, 36, 55-57 and 59*

Dependent claims 21, 36, 55-57 and 59 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mulhauser as applied to claims 1, 20, 29, 35, 54 and 58 above, and in further view of Gianturco (U.S. Patent No. 5,258,000). Applicants respectfully traverse these rejections.

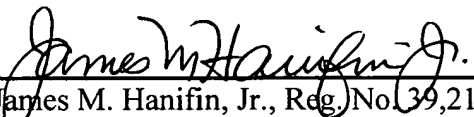
Without acceding to the propriety of these rejections advanced by the Examiner, claim 21, claim 36, and claims 55-57 and 59 respectively depend from independent claims 1, 29 and 54 and are patentable for at least the same reasons set forth above.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the undersigned at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

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